510(k) Summary

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR §807.92, the following summary of information is provided:

A. Submitted by:

Olga Lewis
Regulatory Affairs Specialist
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Telephone: (858) 909-1800

DEC 2 4 2013

Date Prepared: August 19, 2013

B. Device Name

Trade or Proprietary Name:	*NuVasive® CoRoent® Sterile Implants System*
Common or Usual Name:	Intervertebral Body Fusion Device; Spinal Intervertebral Body Fixation Orthosis
Classification Name:	Intervertebral Body Fusion Device; Spinal Intervertebral Body Fixation Orthosis
Device Class:	Class II
Classification:	21 CFR § 888.3080 and § 888.3060
Product Code:	MAX, MQP

C. Predicate Devices

The subject *NuVasive CoRoent Sterile Implants System* is substantially equivalent to the predicate devices, *NuVasive CoRoent System* (K071795) and *Alphatec Spine Epicage Interbody Fusion Device* (K130548).

D. Device Description

The *CoRoent Sterile Implants* are manufactured from PEEK-Optima® LT-1 conforming to ASTM F2026 and titanium alloy conforming to ASTM F136 and ISO 5832-3. The implants are offered gamma sterilized. The implants are available in a variety of different shapes and sizes to suit the individual pathology and anatomical conditions of the patient. The device is intended to be used with supplemental internal spinal fixation systems that are cleared by the FDA for use in the lumbar spine.

E. Intended Use

The *NuVasive® CoRoent Sterile Implants System* is a device system indicated for the following:

Intervertebral Body Fusion

The *NuVasive CoRoent Sterile Implants System* is indicated for intervertebral body fusion of the spine in skeletally mature patients. The System is designed for use with autogenous bone graft to facilitate fusion.

The *CoRoent Sterile Implants System* is intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar devices are to be used in patients who have had at least six months of non-operative treatment.

The System is intended to be used with supplemental internal spinal fixation systems that are cleared by the FDA for use in the lumbar spine.

Partial Vertebral Body Replacement

The *NuVasive CoRoent Sterile Implants System* may also be used as a partial vertebral body replacement device indicated for use in the thoracolumbar spine (T1 to L5) to replace a diseased or damaged vertebral body caused by tumor or fracture, to restore height of a collapsed vertebral body, and to achieve decompression of the spinal cord and neural tissues. The System is intended to be used with supplemental internal spinal fixation systems that are cleared by the FDA for use in the thoracic and lumbar spine. Allograft or autograft material may be used at the surgeon's discretion.

F. Technological Characteristics

As was established in this submission, the subject *NuVasive CoRoent Sterile Implants System* is substantially equivalent to other predicate devices cleared by the FDA for commercial distribution in the United States. The subject device was shown to be substantially equivalent and have equivalent technological characteristics to its predicate device through comparison in areas including design, labeling/intended use, material composition, and function.

G. Performance Data

To establish substantial equivalence with predicate devices, test data is provided as evidence that gamma sterilization does not negatively affect mechanical properties of PEEK-Optima® LT-1 material. Additionally, gamma sterilization validation, sterile packaging performance validation and the integrity of the sterile barrier over time validation were performed to qualify new packaging and sterilization method for the *CoRoent Sterile Implants System*.

The results demonstrate that the subject *NuVasive CoRoent Sterile Implants System* is substantially equivalent to the predicate devices.

H. Conclusions

Based on the indications for use, technological characteristics, and comparison to predicate devices, the subject *NuVasive CoRoent Sterile Implants System* has been shown to be substantially equivalent to legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 24, 2013

NuVasive, Incorporated
Ms. Olga Lewis
Regulatory Affairs Specialist
7475 Lusk Boulevard
San Diego, California 92121

Re: K132601
Trade/Device Name: NuVasive® CoRoent® Sterile Implants System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, MQP
Dated: November 22, 2013
Received: November 25, 2013

Dear Ms. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132601

Device Name: *NuVasive® CoRoent® Sterile Implants System*

Indications For Use:

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD

Division of Orthopedic Devices